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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,560

Applicant(s)

STRAUME ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5 and 6 is/are allowed.
- 6) ☒ Claim(s) 4 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 9/10/04. Claims 1, 3, and 4 have been amended. Claims 1-26 are pending. Claims 7-25 are withdrawn from prosecution as being drawn to non-elected inventions. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

2. Applicant's remarks are addressed in a single section following the rejections.
3. Claims 7-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/28/04.

Drawings

4. The newly filed drawing sheets containing figures 5-8 are approved.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. MPEP 2163.06 notes "If new matter is added to the claims, the examiner

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should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement.

In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

In the instantly rejected claims, the new limitation of "the solid support comprises a magnetically responsive bead" in claim 26 appears to represent new matter. Claim 26 was added to the international application by Article 34 amendment, and as such is not considered part of the specification as originally filed. No specific basis for this limitation was identified in the specification, nor did a review of the specification by the examiner find any basis for the limitation. The "solid support" of claim 1 refers to the fact that the magnetically non-responsive bead is distinguishable from the first bead by attachability to a solid support. The specification at page 16 recites a number of possible such solid supports, but does not include a magnetic bead as one of the options. Since no basis has been identified, the claim is rejected as incorporating new matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroda *et al.* (1993, JP05-281230) in view of Ahern (The Scientist, Vol. 9, No. 15, p. 20, July 1995; Internet copy of article provided in 5 pages, obtained 12/22/98 at www.the-scientist.library.upenn.edu/yr1995/july/tools_950724.html).

Kuroda *et al.* teach a kit comprising (a) a first probe-bead complex comprising a first hybridization probe configured for hybridizing to the first nucleotide sequence type coupled to a magnetically responsive first bead via a first pair of complexing agents, and (b) a second probe-bead complex comprising a second hybridization probe configured for hybridizing to the second nucleotide sequence type coupled to a magnetically non-responsive second bead, which comprises a feature distinguishable from the first bead by size, charge, color, or attachability to a solid support, via a second pair of complexing agents.

A machine translation of the Japanese patent is provided attached to the copy of the Japanese patent. In Example 2, Kuroda *et al.* teach a first nucleic acid probe coupled to a magnetic bead and in Example 3, Kuroda *et al.* teach a second nucleic acid probe (of different sequence from the first probe) coupled to a non-magnetic bead that comprises a feature distinguishable from the first bead by its fluorescent color. Kuroda *et al.* teach kits comprising the reagents for the practice of their method (§ 14, for example).

Kuroda *et al.* do not teach kits which comprise instructions.

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Ahern provides discussion on biochemical reagents kits and the many advantages offered by such kits. Ahern teaches that researchers can purchase kits that supply all of the necessary reagents for a particular assay and “even provides them with detailed instructions to follow (printout, p. 4, second ¶).”

It would have been obvious at the time the invention was made to have modified the kit taught by Kuroda *et al.* so as to have included instructions with the kit because at the time the invention was made it would have been notoriously old and well known to include instructions for use in any kit intended to have a practical use, as discussed by Ahern. The subject matter of those instructions does not serve to distinguish the invention from the prior art because the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. see MPEP 2112.01(III), citing *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983) & *In re Ngai*, 70 USPQ2d 1862 (CA FC 2004). Therefore, in view of the teachings of Kuroda *et al.* in view of Ahern, the claimed invention is prima facie obvious.

Response to Remarks

New Matter Rejection

Applicants point to a number of places in the specification that they argue disclose the use of magnetic beads as a solid support. In each of these cases, the specification is teaching using beads coated with probes or antibodies for the detection of analytes. The rejected claim, however, is directed towards using the beads as a means to separate magnetic and paramagnetic beads. Claim 26 depends from claim 1, and states wherein the solid support is magnetic beads. Turning to claim 1, “the solid support” refers to “a solid support” mentioned in part (a) of the

claim, bridging the last two lines of part (a) of the claim. The claim states that the second bead is distinguishable from the first bead (which is a magnetically responsive bead) by attachability to a solid support. The specification does not provide any teaching that this solid support can be a magnetic bead. The portions of the specification cited by applicant are not relevant to this particular claim limitation. Therefore, the rejection is maintained.

103 Rejection

The rejection of claim 4 under 102 is withdrawn because Kuroda *et al.* do not teach kits which comprise instructions. A 103 rejection has been applied to address this newly added element.

Allowable Subject Matter

9. The instantly claimed methods (claims 1-3, 5-6, and 26) are free of the prior art. The closest prior art is Kuroda *et al.* who teach a method for detecting an analyte in a sample which utilizes reagents that are described in step (a) of each of the method claims. Kuroda *et al.* do not teach or suggest a second separation step, however, wherein the second probe-bead complex and nucleic acids hybridized thereto are separated from the fraction comprising the first nucleotide sequence type according to the properties of the distinguishable feature of the second bead, and a subsequent washing to remove nucleic acids not hybridized to the second hybridization probe. In the case of claims 5-6 which are not limited to hybridization, Kuroda *et al.* do not teach a second separation step as required in step (c) of the claim. Thus, the methods recited in claims 1-3, 5-6 and 26 are free of the prior art.

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10. Claims 1-3 and 5-6 are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Juliet C. Switzer
Examiner
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November 8, 2004